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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,782	02/08/2002	James D. Webb	P-8712.02	2705

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EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2005*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30-32* is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

This is a final Office action. No new grounds of rejection have been presented.

Claim Objections

Claims 14 and 30 are objected to because of the following informalities:

On line 3 of claim 14, "receivers that receive" should be replaced with "receiver that receives;

On line 16 of claim 30, "transmit, any unreceived request" should be replaced with "transmit any request not yet received by the at least one of the plurality of implantable medical devices". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,720,770 to Nappholz et al. in view of US Patent No. 5,371,692 to Draeger et al. Nappholz discloses an external console 27 operating to receive and store at least one request to modify the behavior of an implantable medical device (IMD) 12, the at least one request received from and created by a clinician at a first selected time (col. 6, line 64- col. 7, line 64 of Nappholz). The remote console 27 operates as a

server utilizing memory storage and a telemetry device to connect users in a network to

a centralized store of information (figs. 1 and 6; col. 6, line 64 –col. 7, line 2; col. 7, lines

23-27; col. 7, lines 40-49; col. 8, lines 26-59 of Nappholz), and the description of the

remote console 27 implies that some sort of input device or programmer must be

included to allow the physician to enter instructions for entering the request (col. 7, lines

59-62 of Nappholz). A monitor 14 at a second location remote from the first location

operates to receive the request from the server/remote console 27 (figs. 1, 6; col. 6, line

64-col. 7, line 7; col. 7, line 59-62 of Nappholz), subsequently conduct a programming

telemetry session with the IMD 12, and transmit the at least one request to the IMD 12

at a second selected time (fig. 6; col. 7, line 5-8; col. 7, lines 60-64 of Nappholz), where

figure 6 of Nappholz shows that the programming telemetry session and transmission of

the at least one request to the IMD 12 occurs subsequent to the monitor 14 receiving

the request from the server, since step 252 is shown as the step after step 250. A bi-

directional communications system communicatively couples the server/remote console

27 and the monitor 14 (figs. 1 & 6; col. 7, lines 23-27; col. 7, lines 38-64 of Nappholz).

Nappholz lacks verifying a status of the IMD indicating that the at least one request

safely complies with a current programming state of the IMD.

However, Draeger et al. discloses a system wherein a monitor 13 sends a

request to modify the behavior of a medical device 1, 1" (fig. 3; col. 7, lines 7-16; col. 7,

line 67-col. 8, line 14 of Draeger). After initialization of communication with the medical

device 1, 1" but prior to transmitting the request from the monitor 13 to the medical

device 1, 1", the monitor 13 verifies a status of the medical device 1, 1" indicating that

the request safely complies with a current programming state of the medical device 1, 1"

(col. 8, lines 39-69 of Draeger). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of invention to combine the system of Draeger with

that of Nappholz in order to prevent useless transmission of a program that has already

been downloaded by the medical device (col. 8, lines 47-54 of Draeger).

Regarding claim 7, the second selected time may be substantially later than the

first selected time (fig. 6; col. 7, lines 59-64 of Nappholz) wherein the second selected

time is substantially later such that the first (step 248) and second time (step 252) are

distinguishable as indicated.

Regarding claim 16, the request is transmitted to the IMD only if the request is

determined to be safely compatible (fig. 6 of Draeger et al.)

Claims 4-6, 8, 9, 19, and 22-26 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Nappholz in view of Draeger, as applied to claims 1, 7, and 16

above, and further in view of US Patent No. 6,249,705 to Snell. Nappholz, as modified,

is silent as to encryption or decryption of the request. However, Snell teaches an

apparatus in which information transmitted from a server 102 to a monitor 104 is subject

to security measures including encryption (col. 7, lines 41-54 of Snell), wherein

encryption implies that decryption would also have to occur in order to enable use of the

data transmitted. Therefore, it would have been obvious to one of ordinary skill in the

art at the time of invention to combine the apparatus of Snell with that of Nappholz, as

modified by Draeger, in order to maintain data integrity in the server and monitor, to

maintain appropriate safety levels for the patients being treated by the monitor, to

maintain appropriate configuration controls for the monitors, and to maintain appropriate

protection of patient data confidentiality (col. 7, lines 44-51 of Snell).

Regarding claims 5, 6, and 26, the monitor 14 transmits the request to the IMD

12 using a radio frequency transmitter 128 and the IMD 12 receives the request using a

radio frequency receiver 25 (figs. 1-4A; col. 4, lines 6-11; col. 5, lines 15-18; col. 6, lines

10-16 of Nappholz).

Regarding claims 8 and 9, the monitor transmits the requests to a plurality of

implantable medical devices 12 and the server allows the clinician to submit requests to

at least one of the devices 12 (col. 6, line 64-col. 7, line 15; col. 7, lines 57-64; col. 8,

lines 19-33 of Nappholz).

Regarding claims 19 and 22-25 the use of encryption between the server and the

monitor forms a secure communication link between the first location (server and the

second location (monitor). With further regard to claim 25, the monitor receives the

request at a second time substantially later than the first time at which the programming

initially occurs (fig. 6; col. 7, lines 59-64 of Nappholz), wherein the time difference

between the step 248 of programming the request and the step 250 of transmitting the

request to or receiving the request by the monitor 14 is substantial enough as to be

distinguishable in time, as indicated by figure 6 of Nappholz.

Regarding claim 26, handshaking is employed between the server and the

monitor, wherein handshaking involves notification that a device is ready to send and/or

receive information (col. 8, lines 18-21 of Nappholz; col. 7, lines 51-54 of Snell). Also,

the request is transmitted to medical device only if the current state of the medical

device is determined to be safely compatible (fig. 6 of Draeger).

Claims 2, 3, 10, 13-15, 17, 18, and 27 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Nappholz in view of Draeger and Snell, as applied to claims 4-

6, 8, 9, 19, and 22-26 above, and further in view of US Patent No. 6,132,363 to Freed et

al. Nappholz, as modified, discloses using security measures and data integrity checks

using any combination of hardware and software means, such as communications

protocols to ensure the validity of data exchanged between the monitor and the server,

but is silent as to the details of the communications protocols. However, Freed

discloses a system employing data security and integrity requirements to guard against

unauthorized access to controlling the operating parameters of an implantable medical

device wherein the data security and integrity requirements include verifying that a

person is authorized to submit a request (modify operating parameters) to the IMD (col.

11, line 50-col. 12, line 8; col. 12, line 51-col. 13, line 18 of Freed). Therefore, it would

have been obvious to one of ordinary skill in the art at the time of invention to use the

data security and integrity requirements of Freed as the communications protocol of

Nappholz, as modified by Draeger and Snell, since Nappholz, as modified, discloses

using security measures and data integrity checks in the form of communications

protocols, and Freed teaches user authorization as an appropriate such

communications protocol employing security measures and data integrity checks.

Regarding claim 3, encryption provides a secure communication link between the server and the monitor (col. 7, lines 41-55 of Snell).

Regarding claims 13 and 14, the monitor 14 transmits the request to the IMD 12 using a radio frequency transmitter 128 and the IMD 12 receives the request using a radio frequency receiver 25 (figs. 1-4A; col. 4, lines 6-11; col. 5, lines 15-18; col. 6, lines 10-16 of Nappholz). With further regard to claim 14, the system may monitor and control a plurality of implantable medical devices 12 (col. 8, lines 19-33 of Nappholz).

Regarding claim 18, the system may employ a plurality of IMDs 12 (col. 8, lines 19-33 of Nappholz). A particular IMD 12 is selected by establishing communication between the monitor 14 and the server 27, where the monitor 14 transmits and receives information specific to a particular IMD 12 (fig. 6; col. 7, lines 32-64 of Nappholz).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz, in view of Draeger, Snell, and Freed, as applied to claims 2, 3, 10, 13-15, 17, and 27 above, and further in view of US Patent No. 6,047,325 to Jain et al. Nappholz, as modified, discloses encrypting communication to provide a secure connection, but is silent as to a particular means of doing so. However, Jain teaches that a virtual private network (VPN), created by encryption and authentication, provides a secure network (col. 2, lines 1-6 of Jain). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the VPN of Jain as the secure connection of Nappholz, as modified by Draeger, Snell, and Freed, since Nappholz, as modified, teaches using a secure connection, and Jain discloses a VPN as an appropriate means for doing so.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Nappholz, in view of Draeger, Snell, and Freed, as applied to claims 2, 3, 10, 13-15, 17,

and 27 above, and further in view of US Patent 6,602,469 to Maus et al. Nappholz, as

modified, discloses encrypting communication to provide a secure connection, but is

silent as to a particular means for doing so. However Maus teaches that an Internet

secure socket layer connection is well known in the art as a means of

encryption/decryption (col. 20-25 of Maus). Therefore, it would have been obvious to

one of ordinary skill in the art at the time of invention to use the secure socket layer

connection of Maus as the secure connection of Nappholz, as modified by Draeger,

Snell, and Freed, since Nappholz, as modified, discloses using a secure connection,

and Maus describes a secure socket layer connection as such a secure connection.

Claims 20 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Nappholz, in view of Draeger and Snell, as applied to claims 4-6, 8, 9, 19, and 22-

26 above, and further in view of US Patent No. 6,047,325 to Jain et al. Nappholz, as

modified, discloses encrypting communication to provide a secure connection, but is

silent as to a particular means of doing so. However, Jain teaches that a virtual private

network (VPN), created by encryption and authentication, provides a secure network

(col. 2, lines 1-6 of Jain). Therefore, it would have been obvious to one of ordinary skill

in the art at the time of invention to use the VPN of Jain as the secure connection of

Nappholz, as modified by Draeger and Snell, since Nappholz, as modified, teaches

using a secure connection, and Jain discloses a VPN as an appropriate means for

doing so.

Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Nappholz, in view of Draeger and Snell, as applied to claims 4-6, 8, 9, 19, and 22-

26 above, and further in view of US Patent 6,602,469 to Maus et al. Nappholz, as

modified, discloses encrypting communication to provide a secure connection, but is

silent as to a particular means for doing so. However Maus teaches that an Internet

secure socket layer connection is well known in the art as a means of

encryption/decryption (col. 20, lines 20-25 of Maus). Therefore, it would have been

obvious to one of ordinary skill in the art at the time of invention to use the secure

socket layer connection of Maus as the secure connection of Nappholz, as modified by

Draeger and Snell, since Nappholz, as modified, discloses using a secure connection,

and Maus describes a secure socket layer connection as such a secure connection.

Response to Arguments

Applicant's arguments filed 7/28/05 have been fully considered but they are not

persuasive.

The applicants argue that Nappholz fails to teach transmitting instructions to a

remote monitor, with the remote monitor then subsequently initiating a telemetry

session, the monitor verifying the status/safety of the device and the monitor

programming the device. First, the reference Nappholz alone is not relied upon to teach

the device as claimed. As clearly set for in the above rejection and that of the Office

action field 7/28/05, the combination of Nappholz and Draeger, rather than Nappholz

alone, is relied upon to teach, in particular, a system, as claimed, wherein the monitor

verifies the status/safety of the device prior to the monitor programming the device.

Secondly, in making such an argument, the applicants appear to attribute some special

definition to the term "session" that has not been previously set forth in the specification

or claims of the instant application. The applicants state that Nappholz "is performing a

single telemetry session between the remote console and the ICD 12. However, given

its broadest reasonable definition, the term "session" refers to a period of time devoted

to a specific activity. Therefore, the limitation "programming telemetry session" is

interpreted to mean a period of time devoted to sending programming information. The

period of time during which Nappholz performs step 252 in figure 6 (downloads

parameters from monitor 14 to the IMD 12, see p. 7, lines 63-64 of Nappholz) qualifies

as such a programming telemetry session during which the monitor 14 programs the

device 12.

The applicants further contend that having the monitor of Nappholz verify the

status of the IMD is completely unnecessary and counterintuitive in a situation where

"live" programming is occurring via the remote console, such as shown by the reference

Draeger. Contrary to the applicants' argument, Draeger shows that such status

verification is useful since repetitive transmission of programming that has already

occurred is useless (col. 8, lines 40-62 of Draeger). Even in a live programming

situation, it is possible for the physician or other user to repeat erroneously a

programming command that has already been executed. With respect to the applicants'

view that Draeger "has absolutely nothing to do with the programming of implantable

medical device," Draeger is, in fact, directed to the programming of medical devices in

particular, wherein such programming may occur remotely (col. 2, lines 55-58; col. 6,

lines 50-51; col. 7, lines 8-10; col. 7, line 67-col. 8, line 3 of Draeger).

The combination of Nappholz and Draeger teaches the invention of claims 1, 7,

and 16 of the present application, and the rejections of all claims based on this

combination stand.

Allowable Subject Matter

Claims 30-32 are allowed. The allowability of these claims was addressed in the

previous Office action filed 4/29/05 and is repeated below.

The following is a statement of reasons for the indication of allowable subject

matter:

Regarding claims 30-32, the prior art of record fails to teach or fairly suggest a

system comprising a plurality of monitors, coupled to a bi-directional communication

network to receive and decrypt requests to modify the behavior of at least one of a

plurality of implantable medical devices from the server and to transmit any unreceived

request to the at least one of the plurality of implantable medical devices in an order

created on the programmer, and in combination with all of the other limitations of the

claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone
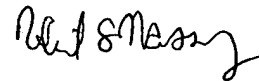
number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ROBERT L. N.
PRIMARY EXAMINER